

spraying the drug/organic mixture into an aqueous solution, wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution; and

concurrently evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles.

Please add the following new claims:

28. A method for preparing poorly water soluble drug particles comprising the steps of:
dissolving a drug in at least one organic solvent to form a drug/organic mixture;
spraying the drug/organic mixture via an atomizing device into an aqueous solution, wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution;
and
rapidly evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles.

REMARKS

Support for the Amendments

The amendments to Claims 1 and 27 to recite that the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution is supported by the specification at page 6, line 20. The amendment to Claim 27 to recite that the organic solvent is rapidly evaporated is supported by the specification at page 7, lines 10 and 19. New Claim 28 is also supported by the claims and specification as originally filed. No new matter is presented with the above amendments.

The 102 Rejections

The Examiner rejected Claims 1-27 under 35 USC 102(b) as being anticipated by US Patent 5,985,248 to Gordon. Amended Claims 1 and 27 recite the step of spraying a drug/organic mixture into an aqueous solution, wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution. Gordon does not teach or suggest spraying the drug/organic mixture into an aqueous solution at or below the liquid level of the aqueous solution.

Moreover, Gordon does not teach or suggest rapidly evaporating the organic solvent in the presence of the aqueous solution, leaving at least a portion of the aqueous behind to form an aqueous dispersion of the drug particles, as is claimed in new Claim 28. Of course, how rapidly the organic solvent is evaporated will depend upon the temperature at which the evaporation takes place. For example, for the temperature range as taught in the specification (10°C to 120°C), rapid evaporation of the organic solvent can occur at anywhere from less than a second to several minutes, for example, 10 minutes or even longer depending on the particular drugs and solvents used.

Evaporation rates for those temperatures in between these lower and upper limits would be readily determined by those skilled in the art.

For these reasons, Amended Claims 1 and 27 are not anticipated by Gordon. Claims 2 through 26 are dependent from Claim 1 and are therefore also not anticipated by Gordon.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration of the application.

Respectfully submitted,

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1. (Amended) A method for preparing poorly water soluble drug particles comprising the steps of:
dissolving a drug in at least one organic solvent to form a drug/organic mixture;
spraying the drug/organic mixture via an atomizing device into an aqueous solution, wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution;
and
concurrently evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles.

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27. (Amended) Poorly water soluble drug particles having an average particle diameter of from 50 nanometers to 20 microns, the drug particles being prepared by a process comprising the steps of:
dissolving the drug in at least one organic solvent to form a drug/organic mixture;
spraying the drug/organic mixture into an aqueous solution, wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution; and
concurrently evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles.

Please add the following new claims:

28. A method for preparing poorly water soluble drug particles comprising the steps of:
dissolving a drug in at least one organic solvent to form a drug/organic mixture;
spraying the drug/organic mixture via an atomizing device into an aqueous solution, wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution;
and
rapidly evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles.